

CLAIMS:

1. A pharmaceutical product comprising any one of the following combinations of therapeutic agents, as a combined preparation for simultaneous, separate or sequential use in the treatment of conditions for which administration of one or more of the therapeutic agents is indicated:

- (i) salmeterol, ciclesonide and tiotropium;
- (ii) formoterol, budesonide and ipratropium;
- (iii) formoterol, ciclesonide and tiotropium;
- (iv) formoterol, budesonide and oxitropium;
- (v) salbutamol, beclomethasone and ipratropium;
- (vi) salbutamol, budesonide and tiotropium;
- (vii) terbutaline, fluticasone and tiotropium;
- (viii) terbutaline, fluticasone and ipratropium;
- (ix) salbutamol, budesonide and ipratropium;
- (x) salmeterol, fluticasone and ipratropium;
- (xi) salmeterol, budesonide and ipratropium;
- (xii) salmeterol, fluticasone and tiotropium; and
- (xiii) formoterol, budesonide and tiotropium;

wherein the above therapeutic agents can optionally be present as a pharmaceutically acceptable salt or ester thereof, or in enantiomerically pure form or as a racemic mixture.

2. A pharmaceutical product according to claim 1, which comprises any one of the following combinations of therapeutic agents:

- (i) salmeterol, ciclesonide and tiotropium bromide;
- (ii) formoterol, budesonide and ipratropium;
- (iii) formoterol, ciclesonide and tiotropium bromide;
- (iv) formoterol, budesonide and oxitropium;
- (v) salbutamol sulphate, beclomethasone and ipratropium;
- (vi) salbutamol sulphate, budesonide and tiotropium bromide;
- (vii) terbutaline sulphate, fluticasone and tiotropium bromide;
- (viii) terbutaline sulphate, fluticasone and ipratropium bromide;

- (ix) salbutamol sulphate, budesonide and ipratropium bromide;
- (x) salmeterol, fluticasone propionate and ipratropium bromide;
- (xi) salmeterol, budesonide and ipratropium bromide;
- (xii) salmeterol, fluticasone propionate and tiotropium bromide; and
- (xiii) formoterol, budesonide and tiotropium bromide.

3. A pharmaceutical composition comprising any one of the following combinations of therapeutic agents:

- (i) salmeterol, ciclesonide and tiotropium;
- (ii) formoterol, budesonide and ipratropium;
- (iii) formoterol, ciclesonide and tiotropium;
- (iv) formoterol, budesonide and oxitropium;
- (v) salbutamol, beclomethasone and ipratropium;
- (vi) salbutamol, budesonide and tiotropium;
- (vii) terbutaline, fluticasone and tiotropium;
- (viii) terbutaline, fluticasone and ipratropium;
- (ix) salbutamol, budesonide and ipratropium;
- (x) salmeterol, fluticasone and ipratropium;
- (xi) salmeterol, budesonide and ipratropium;
- (xii) salmeterol, fluticasone and tiotropium; and
- (xiii) formoterol, budesonide and tiotropium;

wherein the above therapeutic agents can optionally be present as a pharmaceutically acceptable salt or ester thereof, or in enantiomerically pure form or as a racemic mixture, together with a pharmaceutically acceptable carrier or excipient therefor.

4. A composition according to claim 3, which comprises any one of the following combinations of therapeutic agents:

- (i) salmeterol, ciclesonide and tiotropium bromide;
- (ii) formoterol, budesonide and ipratropium;
- (iii) formoterol, ciclesonide and tiotropium bromide;
- (iv) formoterol, budesonide and oxitropium;
- (v) salbutamol sulphate, beclomethasone and ipratropium;

- (vi) salbutamol sulphate, budesonide and tiotropium bromide;
- (vii) terbutaline sulphate, fluticasone and tiotropium bromide;
- (viii) terbutaline sulphate, fluticasone and ipratropium bromide;
- (ix) salbutamol sulphate, budesonide and ipratropium bromide;
- (x) salmeterol, fluticasone propionate and ipratropium bromide;
- (xi) salmeterol, budesonide and ipratropium bromide;
- (xii) salmeterol, fluticasone propionate and tiotropium bromide; and
- (xiii) formoterol, budesonide and tiotropium bromide.

5. A composition according to claim 3 or 4, wherein the anti-cholinergic of the composition is present in an amount 0.001wt% to 0.5wt% based on the weight of the total composition.

6. A composition according to any of claims 3 to 5, wherein the  $\beta$ -2 agonist of the composition is present in an amount 0.001wt% to 0.5wt% based on the weight of the total composition.

7. A composition according to any of claims 3 to 6, wherein the steroid of the composition is present in an amount 0.001wt% to 0.5wt% based on the weight of the total composition.

8. A composition according to any of claims 3 to 7, in a form suitable for administration by inhalation.

9. A composition according to claim 8, in the form of an aerosol.

10. A composition according to claim 9, which further comprises a propellant selected from the group consisting of 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane, monofluorotrichloromethane and dichlorodifluoromethane, or any mixture of two or more thereof.

11. A composition according to claim 9 or 10, further comprising a co-solvent.

12. A composition according to claim 11, wherein the co-solvent is ethanol.
13. A composition according to any of claims 9 to 12, further comprising a surface-active agent.
14. A composition according to claim 13, wherein the surface-active agent is oleic acid, lecithin, or sorbitol trioleate.
15. A composition according to any of claims 9 to 14, which comprises any one of the following combinations of therapeutic agents:
- (i) salmeterol, ciclesonide and tiotropium;
  - (ii) formoterol, budesonide and ipratropium;
  - (iii) formoterol, ciclesonide and tiotropium;
  - (iv) formoterol, budesonide and oxitropium;
  - (v) salbutamol, beclomethasone and ipratropium;
  - (vi) salbutamol, budesonide and tiotropium;
  - (vii) terbutaline, fluticasone and tiotropium;
  - (viii) salmeterol, fluticasone and tiotropium; and
  - (ix) formoterol, budesonide and tiotropium;

wherein the above therapeutic agents can optionally be present as a pharmaceutically acceptable salt or ester thereof, or in enantiomerically pure form or as a racemic mixture.

16. A composition according to claim 15, which comprises any one of the following combinations of therapeutic agents:
- (i) salmeterol, ciclesonide and tiotropium bromide;
  - (ii) formoterol, budesonide and ipratropium;
  - (iii) formoterol, ciclesonide and tiotropium bromide;
  - (iv) formoterol, budesonide and oxitropium;
  - (v) salbutamol sulphate, beclomethasone and ipratropium;
  - (vi) salbutamol sulphate, budesonide and tiotropium bromide;
  - (vii) terbutaline sulphate, fluticasone and tiotropium bromide;

- (viii) salmeterol, fluticasone propionate and tiotropium bromide; and
  - (ix) formoterol, budesonide and tiotropium bromide.
17. A metered dose inhaler which contains a composition as defined in any of claims 9 to 16.
18. A composition according to claim 8, in the form of an inhalation powder.
19. A composition according to claim 18, which comprises lactose as the excipient.
20. A composition according to claim 18 or 19, which comprises any one of the following combinations of therapeutic agents:
- (i) salmeterol, ciclesonide and tiotropium;
  - (ii) formoterol, budesonide and ipratropium;
  - (iii) formoterol, ciclesonide and tiotropium;
  - (iv) salbutamol, beclomethasone and ipratropium;
  - (v) salbutamol, budesonide and tiotropium;
  - (vi) terbutaline, fluticasone and tiotropium;
  - (vii) salmeterol, fluticasone and tiotropium; and
  - (viii) formoterol, budesonide and tiotropium;
- wherein the above therapeutic agents can optionally be present as a pharmaceutically acceptable salt or ester thereof, or in enantiomerically pure form or as a racemic mixture.
21. A composition according to claim 20, which comprises any one of the following combinations of therapeutic agents:
- (i) salmeterol, ciclesonide and tiotropium bromide;
  - (ii) formoterol, budesonide and ipratropium;
  - (iii) formoterol, ciclesonide and tiotropium bromide;
  - (iv) salbutamol sulphate, beclomethasone and ipratropium;
  - (v) salbutamol sulphate, budesonide and tiotropium bromide;
  - (vi) terbutaline sulphate, fluticasone and tiotropium bromide.
  - (vii) salmeterol, fluticasone and tiotropium; and

(viii) formoterol, budesonide and tiotropium.

22. A dry powder inhaler which contains a composition as defined in any of claims 18 to 21.

23. A composition according to claim 8, in the form of a propellant free inhalation solution or suspension.

24. A composition according to claim 23, which comprises any one of the following combinations of therapeutic agents:

- (i) terbutaline, fluticasone and ipratropium;
- (ii) salbutamol, budesonide and ipratropium;
- (iii) salmeterol, fluticasone and ipratropium;
- (iv) salmeterol, budesonide and ipratropium;
- (v) salmeterol, fluticasone and tiotropium; and
- (vi) formoterol, budesonide and tiotropium;

wherein the above therapeutic agents can optionally be present as a pharmaceutically acceptable salt or ester thereof, or in enantiomerically pure form or as a racemic mixture.

25. A composition according to claim 24, which comprises any one of the following combinations of therapeutic agents:

- (i) terbutaline sulphate, fluticasone and ipratropium bromide;
- (ii) salbutamol sulphate, budesonide and ipratropium bromide;
- (iii) salmeterol, fluticasone propionate and ipratropium bromide;
- (iv) salmeterol, budesonide and ipratropium bromide;
- (v) salmeterol, fluticasone propionate and tiotropium bromide; and
- (vi) formoterol, budesonide and tiotropium bromide.

26. A composition according to any of claims 23 to 25, in a form suitable for use with a nebuliser.

27. Use of any one of the following combinations in the manufacture of a medicament for

the prophylaxis or treatment of conditions for which administration of one or more of the therapeutic agents is indicated:

- (i) salmeterol, ciclesonide and tiotropium;
- (ii) formoterol, budesonide and ipratropium;
- (iii) formoterol, ciclesonide and tiotropium;
- (iv) formoterol, budesonide and oxitropium;
- (v) salbutamol, beclomethasone and ipratropium;
- (vi) salbutamol, budesonide and tiotropium;
- (vii) terbutaline, fluticasone and tiotropium;
- (viii) terbutaline, fluticasone and ipratropium;
- (ix) salbutamol, budesonide and ipratropium;
- (x) salmeterol, fluticasone and ipratropium;
- (xi) salmeterol, budesonide and ipratropium;
- (xii) salmeterol, fluticasone and tiotropium; and
- (xiii) formoterol, budesonide and tiotropium;

wherein the above therapeutic agents can optionally be present as a pharmaceutically acceptable salt or ester thereof, or in enantiomerically pure form or as a racemic mixture.

28. Use according to claim 27, which comprises any one of the following:

- (i) salmeterol, ciclesonide and tiotropium bromide;
- (ii) formoterol, budesonide and ipratropium;
- (iii) formoterol, ciclesonide and tiotropium bromide;
- (iv) formoterol, budesonide and oxitropium;
- (v) salbutamol sulphate, beclomethasone and ipratropium;
- (vi) salbutamol sulphate, budesonide and tiotropium bromide;
- (vii) terbutaline sulphate, fluticasone and tiotropium bromide;
- (viii) terbutaline sulphate, fluticasone and ipratropium bromide;
- (ix) salbutamol sulphate, budesonide and ipratropium bromide;
- (x) salmeterol, fluticasone propionate and ipratropium bromide;
- (xi) salmeterol, budesonide and ipratropium bromide;
- (xii) salmeterol, fluticasone propionate and tiotropium bromide; and
- (xiii) formoterol, budesonide and tiotropium bromide.

29. Use according to claim 27 or 28, for the manufacture of a medicament for the treatment of inflammatory or respiratory tract diseases, by simultaneous or successive administration.

30. Use according to claim 29, for the manufacture of a medicament for the treatment of asthma and/or chronic obstructive pulmonary disease (COPD), by simultaneous or successive administration.

31. A method for the prophylaxis or treatment of inflammatory or respiratory tract diseases, said method comprising administering either sequentially or simultaneously, to a patient in need thereof, a therapeutically effective amount of any one of the following combinations:

- (i) salmeterol, ciclesonide and tiotropium;
- (ii) formoterol, budesonide and ipratropium;
- (iii) formoterol, ciclesonide and tiotropium;
- (iv) formoterol, budesonide and oxitropium;
- (v) salbutamol, beclomethasone and ipratropium;
- (vi) salbutamol, budesonide and tiotropium;
- (vii) terbutaline, fluticasone and tiotropium;
- (viii) terbutaline, fluticasone and ipratropium;
- (ix) salbutamol, budesonide and ipratropium;
- (x) salmeterol, fluticasone and ipratropium;
- (xi) salmeterol, budesonide and ipratropium;
- (xii) salmeterol, fluticasone and tiotropium; and
- (xiii) formoterol, budesonide and tiotropium;

wherein the above therapeutic agents can optionally be present as a pharmaceutically acceptable salt or ester thereof, or in enantiomerically pure form or as a racemic mixture.

32. A method according to claim 31, which comprises administering either sequentially or simultaneously, to a patient in need thereof, a therapeutically effective amount of any one of



the following combinations:

- (i) salmeterol, ciclesonide and tiotropium bromide;
- (ii) formoterol, budesonide and ipratropium;
- (iii) formoterol, ciclesonide and tiotropium bromide;
- (iv) formoterol, budesonide and oxitropium;
- (v) salbutamol sulphate, beclomethasone and ipratropium;
- (vi) salbutamol sulphate, budesonide and tiotropium bromide;
- (vii) terbutaline sulphate, fluticasone and tiotropium bromide;
- (viii) terbutaline sulphate, fluticasone and ipratropium bromide;
- (ix) salbutamol sulphate, budesonide and ipratropium bromide;
- (x) salmeterol, fluticasone propionate and ipratropium bromide;
- (xi) salmeterol, budesonide and ipratropium bromide;
- (xii) salmeterol, fluticasone propionate and tiotropium bromide; and
- (xiii) formoterol, budesonide and tiotropium bromide.

33. A method according to claim 31 or 32, for the treatment of asthma and / or chronic obstructive pulmonary disease (COPD), by simultaneous or successive administration.